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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/685,505   | 10/16/2003  | Christine Noel       | 231893US0           | 5083             |
| 22850  | 7590        | 02/13/2009           | EXAMINER            |                  |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      |                     | YU, GINA C       |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
|  |             | 1611                 |                     |                  |
| NOTIFICATION DATE  |             |                      | DELIVERY MODE       |                  |
| 02/13/2009   |             |                      | ELECTRONIC          |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/685,505             | NOEL ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | GINA C. YU             | 1611                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 September 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,6 and 8-24 is/are pending in the application.  
 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 6, 8-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 19, 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present amendment now requires that at least one elastomeric organopolysiloxane is "dispersed in the oily phase", and also recites "wherein the glycine derivative is present in an amount sufficient to disperse the elastomeric organopolysiloxane in the oily phase". The original disclosure does not appear support that the glycine derivatives disperses or aids dispersing the silicone polymer in the oily

phase. Also lacking from the disclosure is an amount sufficient to disperse the silicone polymer in the oily phase. While the specification teaches a suitable and preferred amount of the amino acid for the invention, one of ordinary skill in the art would not have necessarily found that the disclosure refers to an effective amount to disperse the elastomeric organopolysiloxane in the oily phase as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 8-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, “an amount sufficient to disperse the elastomeric organopolysiloxane in the oily phase”. Applicant’s specification does not define what this amount is, and the metes and bounds of the scope of the limitation is not clear.

The remaining claims are rejected as they depend on an indefinite base claim.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 6, 8-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/03952 in further view FR 2771632 to Stoltz or US 20010002257 (English equivalent).**

WO '952 teaches skin care composition comprising silicone elastomer and a skin care active. See abstract. The composition may be in an oil-in-water emulsion. See page 32, lines 15-20 and examples. The composition comprises silicone elastomer in an amount of 1-20%. The organopolysiloxane is preferably an addition reaction curing organopolysiloxane in the presence of a platinum catalyst. The instant organopolysiloxane is taught. See pages 10-14. The carrier for the elastomer serves to suspend and swell the elastomer particles to provide elastic, gel-like matrix. The carrier is used in an amount of 5-50% and may be volatile or non-volatile oil. See page 14. The composition further comprises thickening agents including carboxylic acid polymers, polyacrylate polymers, polysaccharides, gums, and instant polyacrylamide polymer (Sepigel) in the amount of 0.1-5%. See page 19-22 and particularly page 20, line 30 to page 21, line 7. WO '952 teaches the use of active agents including anti-wrinkles agents such as N-acetyl-derivatives, for instance N-acetyl-cysteine (see page 46, line 24) and antioxidants such as methionine, proline, or lysine in an amount of 0.1-10% to provide UV protection (see page 48, line 20). The composition may be formulated into facial skin cosmetics, eye cosmetics, anti-wrinkle creams, lip cosmetics, foundations, etc. The composition is useful in reducing the appearance of wrinkles, scars, skin roughness, blemishes, pores, etc.

The reference does not teach the instant lipoamino acid.

Stoltz teaches the use of N-acyl amino acids for formulating cosmetic compositions that provides soothing/protecting properties, retards skin aging, and

provides disinfecting properties to treat acne. The amino acids taught are undecylenoyl glycine and octanoyl glycine. See abstract.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of WO '952 and Stoltz and utilize the instantly claimed amino acid. One would have been motivated to do so since Stoltz teaches the undecylenoyl glycine and octanoyl glycine provides soothing/protecting properties, retards skin aging, provides disinfecting properties to treat acne and WO'952 teaches anti-wrinkles agents such as amino acid derivatives, the use of antioxidants such as methionine, acne actives, and soothing/skin healing actives. Thus, a skilled artisan would have been motivated to utilize the instant amino acid to provide a cosmetic composition that provides all three skin benefits of treating acne, retarding aging, and soothing the skin in a single formulation. A skilled artisan would have reasonably expected success since Stoltz teaches the use of various skin active agents including lipoamino acids.

**Claims 1, 6, 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1055406 or US 6,465,402, the English equivalent in view of Fotinos (US 6,346,255).**

Lorant teaches an oil-in-water emulsion comprising an organopolysiloxane elastomer in the oily phase and a water-soluble polymer in the aqueous phase. The oil-in-water emulsions are stable and thus do not contain a conventionally used surfactant. Lorant teaches emulsifiers are potentially irritating the skin, eyes and scalp and thus it is

Art Unit: 1611

advantageous to formulate an emulsion without using emulsifiers to stabilize the emulsion. The compositions provide fresh and comfortable feel during application to the skin, unlike conventional compositions. See abstract and column 1, lines 18-36.

Lorant teaches the use of  $\alpha, \omega$  dimethylvinylpolydimethylsiloxane. See column 4, line 50 and the elastomer gel is utilized in an amount of 0.03-40% and preferably 1.5-20%. See column 5, lines 59-66. The water-soluble polymers that are suitable include carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers and copolymers; vinyl ether copolymers; or cationic polymers, such as polyquaternium. Preferable acrylamide copolymers include the crosslinked copolymer of acrylamide and of 2-acrylamido-2-methylpropanesulphonic acid, in particular the mixture sold under the name Sepigel 305. The polymer is used in an amount from 0.1 to 10%, preferably 0.2 to 5%, and more preferably from 0.5 to 2%. See column 6, line 5 to column 9, line 40. The oils in the oil phase include non-volatile and volatile oils and the oily phase can range from 1 to 50%. See column 9, line 40 to column 10, line 25. The composition comprises active agent in the amount of 0.01-30% and may be antioxidants, lipophilic active agents, etc. Preferably the active agents include moisturizing agents; keratolytic agents; salicylic acid and its derivatives; vitamins; depigmenting agents; slimming agents; screening agents; and any active principle appropriate for the final purpose of the composition. See column 10, lines 32-60. The composition is suitable for treating dry skin and/or dry lips. See column 11, lines 1-7.

Lorant does not teach the use of the instant lipophilic amino acids.

Fotinos teaches a method of improving skin appearance with a skin permeation enhancer and an active agent. See abstract. Fotinos teaches the use of various lipoamino acids such as acylation products, which are anti-elastase and anti-collagenase agents (anti-wrinkle agents); the use of lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seboregulators; lipoamino acids such as lysine PCA and related compound as hydratives. See column 7, lines 36-65.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Lorant and Fotinos and utilize lipoamino acids as the active agent in Lorant's composition. One would have been motivated to do so since Fotinos teaches lipoamino acids have a large number of applications in the cosmetic field including anti-wrinkle agents, antioxidants, hydrating agents, and seboregulators and Lorant teaches the use of any skin active agent including antioxidants and moisturizing agents, depending on the final purpose of the composition. Therefore, the selection of the active agent is *prima facie* obvious depending on the desired aesthetic benefit provided by the skin care composition. Furthermore, a skilled artisan would have been motivated to use capryloyl glycine in particular if one desired to provide a composition that controls sebum, which causes acne.

#### ***Response to Arguments***

Applicant's arguments filed on November 19, 2008 have been fully considered but they are not persuasive.

Applicant relies on the Rule 132 declaration filed on July 24, 2007 and continues to assert that the emulsions containing the claimed glycine derivatives are stable, whereas emulsions containing different amino acids (e.g., methionine) are not and have large oily globules throughout. In response, the comparison was not made under the same condition because the invention sample contained triethanolamine; it is not clear whether triethanolamine could have also affected agglomeration of the elastomer in the comparison. Nor was triethanolamine or any other solvents used in the original invention to solubilized the lipoamino acid. Thus, applicant's arguments based on the July 24, 2007 declaration are not viewed persuasive.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1611

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/  
Primary Patent Examiner, Art Unit 1611